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MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MINNEAPOLIS, MN 55432-9924

EXAMINER
SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/682,220	SHAH ET AL.	
	Examiner	Art Unit	
	Kathleen Sonnett	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 25 June 2007.

2a)☐ This action is **FINAL**.　　2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10,13-29,31-37 and 70-99 is/are pending in the application.

4a) Of the above claim(s) 70-99 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10,13-29,31-37, and 70-99 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All　b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's amendments filed 6/25/2007 have overcome the previously presented 35 U.S.C. 102 and 103 rejections of the claims and the rejections have been withdrawn.

2. In the previous office action mailed 3/23/2007, the examiner rejected claim 33 under 35 USC 112 2nd paragraph for failing to provide antecedent basis for "the RF die". However, this rejection should have been directed to claim 34 and has been presented correctly in this office action.

3. Applicant's arguments with respect to the double patenting rejections previously presented have been considered but are moot in view of the new ground(s) of double patenting rejection necessitated by amendment and presented below.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-10,13-29, and 31-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 recites the limitation "the polymeric material" in line 13 of the claim. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 34 recites the limitation "the RF die". There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. **Claims 1-6, 9-10, 35, and 36** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,065,394 in view of Cho (US. 5,109,830) and Hibbs et al. (US 5,300,032). Claim of '394 claims the particulars of the outer sheath but does not claim an inner sheath with a radiopaque and echogenic tip. However, Cho teaches that it is well known to employ an inner sheath (catheter) in an outer sheath wherein at least the distal tips of each sheath are radiopaque so that both can be imaged. Since claim 1 of '394 claims that the outer sheath tip is echogenic as well as radiopaque, it would be obvious to make the tip of the inner sheath echogenic as well as radiopaque so that when the outer sheath is viewed using ultrasound, the inner sheath is also visible. Hibbs et al. teaches that it is old and well known to employ a distal tip on a sheath that is about 0.5 inches and has a hardness of 25 to 75D in order to form a more flexible soft tip. The rest of the sheath has a greater stiffness. This anticipates a range of 25 to 35D since Hibbs teaches every value within the range of 25 to 35D. It would have been obvious to one skilled in the art to modify '394 to include an inner sheath that is similarly radiopaque and echogenic at its

tip as taught by Cho, the tip being about 0.5 inches long and having a hardness of 25 to 35D as taught by Hibbs in order to provide an additional sheath that can traverse tortuous paths with an atraumatic tip that minimizes damage to surrounding tissue. The length of 0.5 inches reads on the claimed ranges of claims 1,4, and 5. However, the claimed range of claim 3 is being considered obvious since it is well known to adjust tip length depending on the intended use of the device and is being considered a matter of design choice to one of ordinary skill in the art which fails to patentably distinguish the claimed invention from claim 1 of '394 in view of Cho and Hibbs. It is noted that applicant has not disclosed any particular advantage gained, purpose served, or problem solved by using a tip between 0.08 – 0.2 inches as opposed to the other claimed ranges.

9. Regarding claims 2 and 6, it would have been obvious to one skilled in the art to use tungsten carbide particles having an average size less than or equal to approximately 500 nanometers to form the radiopaque and echogenic portion of the inner sheath since these particles are used to form the radiopaque portion of the outer sheath in claim of '394 and would allow consistent imaging properties between the two sheaths. The same reasoning can be applied to claims 9 and 10 of the instant application. Since the outer sheath uses approximately 70 to 75% by weight of particles, it would have been obvious to one skilled in the art to use the same weight percent of particles in the inner sheath with the expectation of achieving a radiopaque and echogenic tip.

10. **Claims 1, 6, 7, and 8** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,065,394 in view of Cho (US. 5,109,830), Hibbs et al. (US 5,300,032), and Zhang et al. (US 6,387,981) or Sarkis et al. (U.S. 5,921,933). Claim 1 of '394 in view of Hibbs and Cho includes an inner sheath with the same radiopaque and echogenic properties of the outer sheath but fails to disclose

nanoparticles with diameters of between 100 and 200 nanometers. However, such diameters (around 100 nanometers) are well known for use with tungsten particles to impart radiopacity to devices as taught by Zhang and Sarkis et al. (abstract) and would have been an obvious modification of claim 1 in view of Hibbs and Cho since one skilled in the art would have had a reasonable expectation of success with particles of this size.

11. **Claims 13 and 15-18** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,065,394 in view of Cho, Hibbs, and further in view of Li et al. (US 6,066,126). Claim 1 of '394 in view of Cho and Hibbs claims the invention substantially but fails to claim that the distal tip of the second sheath includes first and second resilient preformed curves. However, Li teaches that it is old and well known to provide resilient preformed curves in a catheter in order to help guide the catheter through blood vessels to a desired position. Therefore, it would have been obvious to one skilled in the art to further modify the invention of claim 1 of '394 to include first and second preformed curves in the tip of the inner sheath in order to facilitate travel of the device within a patient's vasculature. In particular, the first curve (32) sweeps out an angle of approximately 40-90 degrees and is included in the tip portion which has a length greater than 0.08 inches. Segment 34 along can have a length of 2cm (col. 3 ll. 19-20). The tip also includes a second resilient curve preformed curve (28) that sweeps out an angle of up to about 90 degrees. Since both curves sweep out angles of 90 degrees, together they sweep out an angle greater than approximately 90 degrees.

12. **Claims 13, 17, 19, and 20** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,065,394 in view of Cho, Hibbs, and further in view of Rickerd (US 5,322,509). Claim 1 of '394 in view of Cho and Hibbs claims the invention substantially but fails to claim that the distal tip of the second sheath

includes first and second resilient preformed curves. However, Rickerd teaches that it is old and well known to provide resilient preformed curves in a catheter in order to help guide the catheter through blood vessels to a desired position. It would have been obvious to one skilled in the art to further modify the invention of claim 1 of '394 to include first and second preformed curves in the tip of the inner sheath in order to facilitate travel of the device within a patient's vasculature. Rickerd teaches an elongated sheath including a distal tip, the distal tip (C and D) having a length (about 4.8 cm) greater than or equal to approximately 0.08 inches (about 2.032 mm) having a sheath has first and second resilient curves formed in the tip that form an amplatz shape (see fig. 1).

13. Regarding the angles claimed in claim 19, at the time of the invention, it would have been an obvious matter of design choice to one skilled in the art to employ angles of between 160 and 180 for the first curve and angles between 40 and 80 for the second curve. Rickerd does not disclose the degrees of the angles swept out by each curve (C and D). However, as seen in fig. 1, the first curve "C" appears to be at least twice the size of and in the opposite direction of second curve "D". Since applicant has not disclosed any criticality regarding the degree.ranges such as a particular problem solved, advantage achieved, or a particular usage that is dependent on these angles, and the figures of Rickerd suggest angles that are around (120-160) and (40-60) degrees, it appears that the device of Rickerd would perform the function of snaking through coronary arteries equally well with the curves of Rickerd or the claimed curves.

14. **Claims 13, 17, 20-24, 26, and 28** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,065,394 in view of Cho, Hibbs, and further in view of Tanaka et al. (US 6,039,723). Claim 1 of '394 in view of Cho and Hibbs claims the invention substantially but fails to claim that the distal

tip of the second sheath includes first, second, and third resilient preformed curves. However, Tanaka et al. teaches that it is old and well known to provide resilient preformed curves in a catheter in order to help guide the catheter through blood vessels to a desired position. It would have been obvious to one skilled in the art to further modify the invention of claim 1 of '394 to include first, second, and third preformed curves in the tip of the inner sheath in order to facilitate travel of the device within a patient's vasculature. Regarding claims 13, 17, 20-24, 26, and 28, Tanaka teaches first, second, and third preformed curves (see fig. 1). When taken together, the angles that each one sweeps out will be greater than 100 degrees since the first curve by itself sweeps out an angle of around 180 degrees. The two most distal curves form an amplatz shape. The distal tip also includes a tapered transition (see "232" in fig. 12 and 13).

15. **Claims 13 and 24-27** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,065,394 in view of Cho, Hibbs, and further in view of Lentz (US 6,022,341). Claim 1 of '394 in view of Cho and Hibbs claims the invention substantially but fails to claim that the inner sheath has a tip that includes two resilient preformed curves and a tapered transition. However, Lentz discloses a sheath that includes a tip with two resilient preformed curves and a tapered portion (30) that is proximal to both curves (see fig. 3). Curves and tapered portions along sheaths are well known in the art and it would have been obvious to one skilled in the art to modify the invention of claim 1 of '394 to include two resilient preformed curves and a tapered portion as taught by Lentz in order to facilitate insertion and positioning of the device through tortuous paths.

16. **Claims 13, 17, 21, 28, and 29** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,065,394 in view of Cho, Hibbs, and further in view of Lentz (US 6,022,341) and Rickerd. Claim 1 of '394 in view of Cho and Hibbs claims the invention substantially but fails to claim two preformed curves with

a tapered transition proximal to the curves of the inner sheath taught by Cho and Hibbs. However, Lentz teaches two proximal curves with a tapered transition proximal to the curves and Rickerd teaches including a third curve to further facilitate insertion and positioning of the sheath. It would have been obvious to one skilled in the art to modify the invention of claim 1 of '394 to include three resilient preformed curves and a tapered portion as taught by Lentz and Rickerd in order to facilitate insertion and positioning of the device through tortuous paths.

17. **Claims 31 and 32** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,065,394 in view of Cho, Hibbs, and further in view of Wijayarathna et al. (US 4,563,181). Claim 1 of '394 in view of Cho and Hibbs claims the invention substantially but fails to claim that the tip is coupled to the distal end of a proximal segment of the sheath by means of a butt joint. However, Wijayarathna teaches joining a distal tip to the proximal end of a guide catheter by a heat-fused butt joint (see abstract; col. 3 ll. 44-45). It would have been obvious to join the tip to the proximal portion of the sheath with a heat fused butt joint since this is an old and well known method of joining portions of catheters together.

18. **Claims 33 and 34** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,065,394 in view of Cho, Hibbs, and further in view of Jensen (US 5,160,396). Claim 1 of '394 in view of Cho and Hibbs claims the invention substantially but fails to claim that the tip is coupled to the distal end of a proximal segment of the sheath by means of a butt joint. However, Jensen teaches that it is old and well known to use an RF process using an RF die to form butt joints in catheter sections and also discloses that the die may be used to form tapered tips (see abstract). The method of Jensen has a high rate of repeatability and produces a high quality weld (col. 2 ll. 25-35). It would have been obvious to one of ordinary skill in the art to modify the device of claim 1 of '394

to form the butt joint and a tapered transition on the tip with the RF die of Jensen in order to gain the advantages of a tip that aids in insertion and strong welding points.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

glenn

KCS 8/24/2007

GLENN K. DAWSON
PRIMARY EXAMINER